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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,652

09/29/2005

Patrick Alexandre

125319

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ALEXANDRIA, VA 22320-4850

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,652	<b>Applicant(s)</b> ALEXANDRE ET AL.	
	<b>Examiner</b> ELIZABETH R. MACNEILL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landau et al (US 2002/0188250) in view of Castellano et al (US 5,730,723) and Schwebel et al (US 3,802,430).

Landau teaches a needleless injector with a body (12), an initiation device (34), a compressed gas source (24), a reservoir (14), a housing (24), wherein the gas source is disposed in a cartridge (24) in the housing which may be inserted into the body in an assembled state independently of the other elements in the circuit (Fig 3). The body further comprises an opening (38) which the cartridge closes off. Landau does not teach the use of a pyrotechnic charge.

Castellano teaches that gas powered injectors are equivalents of pyrotechnic charges (Col 4 lines 25-28) but does not discuss the particulars of a pyrotechnic charge.

Schwebel teaches a disposable pyrotechnic injector with a charge (25), a frangible seal (between 25 and 43), a primer (28) and a percussion device (27), and expansion chamber (43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the replaceable cartridge design of Landau with the pyrotechnic

charge of Schwebel since it is well known in the art, as taught by Castellano, that gas powered injectors and pyrotechnic injectors are functional equivalents and may be predictably substituted for one another.

1. Claims 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landau/Castellno/Schwebel as applied to claims 1-4 above, and further in view of Bellhouse et al (US 6,328,714).

Landau does not teach the U-shaped circuit or L-shaped cartridge and housing.

Bellhouse teaches a needleless injector with a body (2), an initiation device (32), a compressed gas source (22), a reservoir (24), a housing (4), wherein the gas source is disposed in a cartridge (20) which maybe inserted into the housing in an assembled state independently of the other elements in the circuit (Fig 7). The body further comprises an opening (56) which the cartridge closes off. Figs 1,3, and 7. The initiation device is a percussive device (32). The circuit forms a U-shape, with the cartridge forming an L-shape (Fig 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use to U-shape and L-shape of Bellhouse with the needleless injection system of Landau as an alternative arrangement for the replaceable pieces which control the pressure of the gas generated.

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1-12 have been considered but are not persuasive. Applicant first argues that the door (initiation device) of Landau must be closed for the device to be considered assembled. This is equivalent to saying that the

plunger of a syringe must be fully depressed for the syringe to be considered assembled. The examiner finds that one of ordinary skill in the art would consider that if the door is attached, the device is assembled, as in Fig 3. Applicant next argues that the initiation device and primer of Schwebel prevent the device from being assembled such that the cartridge can be inserted into the circuit of elements. Schwebel shows that his initiation device is a small plunger (36) which is depressed and then triggers the pyrotechnic reaction through the primer. The cartridge is found in elements 25 and 26, shown with different cross-hatching than the initiation device and expandable chamber in Fig 1. Therefore, one of ordinary skill in the art would recognize that the cartridge is separate from the other parts of the housing. Since Landau teaches that only the cartridge is removable, one of ordinary skill in the art would recognize that the initiation device of Landau and the gas cartridge could be replaced by the initiation device and pyrotechnic cartridge of Schwebel where the initiator pivots open to expose an opening for the cartridge.

### ***Conclusion***

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/  
Examiner, Art Unit 3767

/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767